



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
College Park, MD 20740

9 0 5 2 '02 DEC 16 P3 31
NOV 18 2002

Ms. Kristen Jones
Administrative Assistant
Basic Research, L.L.C.
dba The Carter-Reed Company
5742 West Harold Gatty Drive
Salt Lake City, Utah 84116

Dear Ms. Jones:

This is in response to your letter of October 28, 2002 to the Food and Drug Administration (FDA) pursuant to 21 U.S.C. 343(r)(6) (section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (the Act)). In your letter, you stated that Basic Research, L.L.C., dba The Carter-Reed Company, intends to use the following claims for the dietary supplement **Relacor™** :

"Helps Prevent Stress-Related Abdominal Obesity;"
"Formulated to Help Reduce Subclinical Depression."

21 U.S.C. 343(r)(6) makes clear that a statement included in labeling under the authority of that section may not claim to diagnose, mitigate, treat, cure, or prevent a specific disease or class of diseases. The statements that you are making for this product suggest that it is intended to treat, prevent, or mitigate diseases, namely obesity and depression. These claims do not meet the requirements of 21 U.S.C. 343(r)(6). These claims suggest that this product is intended for use as a drug within the meaning of 21 U.S.C. 321(g)(1)(B), and that it is subject to regulation under the drug provisions of the Act. If you intend to make claims of this nature, you should contact FDA's Center for Drug Evaluation and Research (CDER), Office of Compliance, HFD-310, 7520 Standish Place, Rockville, Maryland 20855.

975-0163

LET654

Page 2 - Ms. Kristen Jones

Please contact us if you require further assistance.

Sincerely yours,

A handwritten signature in black ink, appearing to read "John B. Foret", with a stylized flourish at the end.

John B. Foret

Director

Division of Compliance and Enforcement

Office of Nutritional Products, Labeling
and Dietary Supplements

Center for Food Safety
and Applied Nutrition

Copies:

FDA, Center for Drug Evaluation and Research, Office of Compliance, HFD-300

FDA, Office of the Associate Commissioner for Regulatory Affairs, Office of
Enforcement, HFC-200

FDA, Denver District Compliance, HFR-SW240

BASIC RESEARCH®

5742 West Harold Gatty Drive
Salt Lake City, UT 84116

phone (801) 517-7000

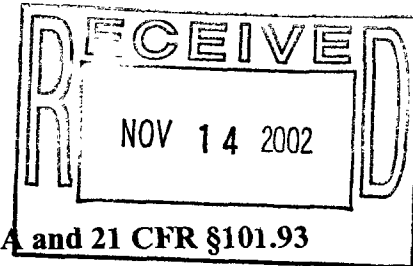
fax (801) 517-7001

website www.BasicResearch.org

October 28, 2002

VIA CERTIFIED MAIL

Food and Drug Administration
200 C Street S.W.
Washington, DC 20204



RE: Notification Pursuant to Section 6 of DSHEA and 21 CFR §101.93

Dear Sir or Madam:

Enclosed please find the Notification Pursuant to Section 6 of DSHEA and 21 CFR §101.93 for the dietary supplement product Relacore™. This notification is on behalf of Basic Research, L.L.C. dba The Carter-Reed Company.

Please review the information at your earliest convenience. Please contact me with any questions of if there is any further information I can provide regarding this matter.

Sincerely,

A handwritten signature in cursive script that reads "Kristen Jones".

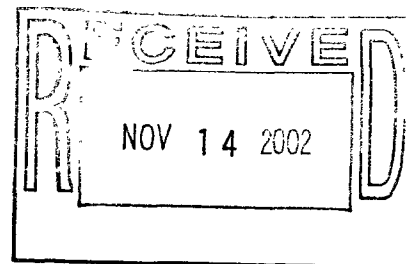
Kristen Jones

Admin. Assistant

/encls.

8.2511

**NOTIFICATION PURSUANT TO
SECTION 6 OF DSHEA
AND 21 CFR § 101.93**



This notification is being filed on behalf of Basic Research, L.L.C. dba The Carter-Reed Company that is the Distributor of the product(s) which bear the statements identified in this notification. Its business address is: 5742 West Harold Gatty Dr, Salt Lake City, Utah 84116. This notification is being made pursuant to Section 6 of DSHEA and Rule 21 C.F.R. § 101.93. The dietary supplement product on whose label or labeling the statements appear is **Relacore™**.

The text of each structure-function statement for which notification is now being given is:

- (Statement 1): "Stress Reducer / Mood Elevator"
- (Statement 2): "Helps Prevent Stress-Related Abdominal Obesity"
- (Statement 3): "Formulated To Help Reduce Stress"
- (Statement 4): "Formulated To Help Reduce Mild Anxiety"
- (Statement 5): "Formulated To Help Reduce Subclinical Depression"
- (Statement 6): "Formulated To Help Fight Mid-Day Fatigue"
- (Statement 7): "Formulated To Help Increase Energy"

The following summary identifies the dietary ingredient(s) or supplement(s) for which a statement has been made:

<u>Statement Number</u>	<u>Identity of Dietary Ingredient(s) or Supplement(s) that is the Subject of the Statement:</u>
1	Relacore™--90ct Box
2	Relacore™--90ct Box
3	Relacore™--90ct Box
4	Relacore™--90ct Box
5	Relacore™--90ct Box
6	Relacore™--90ct Box
7	Relacore™--90ct Box

The following identifies the brand name of each supplement for which a statement is made:

<u>Statement Number</u>	<u>Brand Name</u>	<u>Label or Labeling?</u>
1	Basic Research, L.L.C., dba The Carter-Reed Company	both

82511

2	Basic Research, L.L.C., dba The Carter-Reed Company	both
3	Basic Research, L.L.C., dba The Carter-Reed Company	both
4	Basic Research, L.L.C., dba The Carter-Reed Company	both
5	Basic Research, L.L.C., dba The Carter-Reed Company	both
6	Basic Research, L.L.C., dba The Carter-Reed Company	both
7	Basic Research, L.L.C., dba The Carter-Reed Company	both

I, Daniel B. Mowrey, Ph.D., am authorized to certify this Notification on behalf of Basic Research, L.L.C. dba The Carter-Reed Company. I certify that the information presented and contained in this Notification is complete and accurate, and that Basic Research, L.L.C. dba The Carter-Reed Company has substantiation that each structure-function statement is truthful and not misleading.

Dated this 28th day of October, 2002.

By: _____

Daniel B. Mowrey, Ph.D.

Consultant to Basic Research, L.L.C.
dba The Carter-Reed Company

MFS 12635-12BL9-71

Relacore™

(Relacortin™)

Stress Reducer / Mood Elevator*
Helps Prevent Stress-Related Abdominal Obesity*

Formulated To Help:

- Reduce Stress*
- Reduce Mild Anxiety*
- Reduce Subclinical Depression*
- Fight Mid-Day Fatigue*
- Increase Energy*

90 capsules [Non-Sedative Formula]

Dietary Supplement

CRD Distributed by The Carter-Reed Company

Supplement Facts

Serving Size: 1 capsule
 Servings Per Container: 90

	Amount Per Serving	% Daily Value*
Vitamin C	550mg	550%
Calcium	21.5	2%
for Calcium and phosphorus		
Vitamin B12	5mg	55%
Hydroxy Vitamin B2	7mg	47%
Vitamin B6	17mg	85%
Vitamin B12	3.5mg	35%
Biotin	100mcg	30%
Paracetamol Acid	7.5mg	75%
for calcium phosphorus		
Magnesium	25mg	17%
Relacore™	200mg	
a proprietary blend of:		
Almonds (fruit SE)		
Peanut Power (fruit SE)		
Coconut (fruit SE)		
Macadamia		
ORF		
Peanut (fruit SE)		
Peanut (fruit SE)		
Almonds (fruit SE)		
Peanut (fruit SE)		
Peanut (fruit SE)		

*Percent Daily Values are based on a 2,000 calorie diet
 † Daily Value not established

Distributed by: The Carter-Reed Company
 Salt Lake City, UT 84116 • 1-800-898-5153
 Made in the U.S.A.

Relacore Directions: Take one capsule with a full glass of water, three times per day: morning, noon, and early evening. You may take Relacore with or without food. Do not exceed 3 capsules per day.

WARNING: Do not exceed suggested daily dose. Consult a physician before use. Do not use if you are pregnant or lactating, have a medical condition, or are taking prescription medications. Not intended for use by persons under 40 years of age. If your health-care provider has any questions, ask him or her to call 1-800-898-5153.

Keep out of reach of children.

NOTE: For additional information on this or any other Carter-Reed™ product, please call our experienced customer service representatives at 1-800-898-5153.

Use only as directed. Store at controlled room temperature 15°-30°C/59°-86°F

www.Relacore.com

*These statements have not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease.

©2002 All Rights Reserved



6 81168 10102 2 BR0802742